

# Study of Bone-screw Surface Fixation in Lumbar Dynamic Stabilization

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## Abstract

**Background:** We aimed to use the animal model of dynamic fixation to examine the interaction of the pedicle screw surface with surrounding bone, and determine whether pedicle screws achieve good mechanical stability in the vertebrae.

**Methods:** Twenty-four goats aged 2–3 years had Cosmic<sup>®</sup> pedicle screws implanted into both sides of the L2-L5 pedicles. Twelve goats in the bilateral dynamic fixation group had fixation rods implanted in L2-L3 and L4-L5. Twelve goats in the unilateral dynamic fixation group had fixation rods randomly fixed on one side of the lumbar spine. The side that was not implanted with fixation rods was used as a static control group.

**Results:** In the static control group, new bone was formed around the pedicle screw and on the screw surface. In the unilateral and bilateral dynamic fixation groups, large amounts of connective tissue formed between and around the screw threads, with no new bone formation on the screw surface; the pedicle screws were loose after the fixed rods were removed. The bone mineral density and morphological parameters of the region of interest (ROI) in the unilateral and bilateral dynamic fixation group were not significantly different ( $P > 0.05$ ), but were lower in the fixed groups than the static control group ( $P < 0.05$ ). This showed the description bone of the ROI in the static control group was greater than in the fixation groups. Under loading conditions, the pedicle screw maximum pull force was not significantly different between the bilateral and unilateral dynamic fixation groups ( $P > 0.05$ ); however the maximum pull force of the fixation groups was significantly less than the static control group ( $P < 0.01$ ).

**Conclusions:** Fibrous connective tissue formed at the bone-screw interface under unilateral and bilateral pedicle dynamic fixation, and the pedicle screws lost mechanical stability in the vertebrae.

**Key words:** Bone-screw Interface; Dynamic Fixation; Histomorphology; Mechanical Stability; Micro-computed Tomography

## INTRODUCTION

Spinal fusion and suppression have been the standard surgical intervention for treating lumbar vertebrae instability and lumbar disc herniation over the past several decades.<sup>[1]</sup> However, there is the associated potential problem of increased motion at adjacent segments, with possible increased risk of disc degeneration.<sup>[2,3]</sup> Nonfusion and dynamic posterior stabilization is a possible alternative to fusion for the treatment of degenerative problems in the lumbar spine.<sup>[4-6]</sup>

A large number of clinical studies have found that nonfusion surgery can reduce adjacent segment disc degeneration, and conserve the activity of the surgery section.<sup>[7-10]</sup> However,

when using nonfusion surgery, it is not yet known whether pedicle screws can maintain stability in the complex mechanical environment of the spine. It is also not yet known whether osseous fusion is achieved between bone and screw. Few reports investigated the pedicle screw and bone interface in dynamic fixation.

In this study, we aimed to use the animal model of dynamic fixation to observe the interaction of the screw surface with the surrounding bone tissue, and determine whether the pedicle screws achieve good mechanical stability in the vertebrae.

## METHODS

### Experimental animals

Twenty-four goats were provided by the Animal Laboratory of Medicine School of Jilin University. The goats were aged

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from 2 to 3 years, weighed 65–80 kg, and had lengths of 150–160 cm. The experiment was approved by the Animal Ethics Committee of Medicine School of Jilin University.

### Surgical procedures

Anesthesia was induced via intramuscular ketamine injection. The goats were then placed on the operating table, and anesthesia was maintained using 30 mg/kg of 2.5% intravenous pentobarbital. After determining the location of L2-L5, a 4 cm incision was made 1 cm from the lateral side of the spinous process of L4 and L5. To reduce bleeding and surgical trauma in the goats, blunt dissection was performed between the paravertebral muscles to reveal the L5 superior facet and the proximal transverse process. The lumbar entry point of the screw was the intersection of the midline of the transverse process and the end of the outer edge of the superior articular process. Some of the cortical bone was bitten at the entry point. The pedicle entrance was then expanded with a special curette, reamed with a reamer, and repeated with a tapped thread of the same diameter as the coated titanium pedicle screw. The pedicle channel was probed along the pedicle medial cortical bone to confirm the integrity of the pedicle cortex and randomly implanted with a Cosmic<sup>®</sup> pedicle screw (Arthur N. Ulrich Company, Germany) [Figure 1]. The angle between the direction of the entry point of the pedicle screw and the spinal sagittal plane was approximately 10°, parallel with the disc. Moving up the incision slightly, the same surgical procedure was used to expose the L4 superior facet and implant the pedicle screw.<sup>[11,12]</sup>

Using the same surgical procedure, Cosmic screws were implanted on the same side of the pedicles of L2 and L3 and the contralateral side of L2-L5. The connecting rods were implanted in L2-L3 and L4-L5 of the 12 goats in the bilateral dynamic fixation group. The connecting rods were implanted into one side of the lumbar spine in the remaining 12 goats in the unilateral dynamic fixation group. The side that had no fixation rod was used as a static control group [Figure 2].

The paraspinal muscles and deep fascia were sutured closely, and the surgical incision was covered with sterile gauze.



**Figure 1:** Cosmic<sup>®</sup> pedicle screw (Arthur N. Ulrich Company, Germany).

After surgery, the surgical wounds were disinfected with iodophor twice a day for 10 days. The goats were injected intramuscularly with 320 U/ml penicillin twice a day for 1 week. The sutures were removed after 14 days.

### Postoperative observation

The lumbar spine pedicle screws were taken out after 3 months, and regular specimens were made. These were examined via morphological, microscopic computed tomography (CT) imaging, organization, and biomechanical experiments to determine whether the pedicle screws had good biomechanical stability in the goat lumbar vertebrae in the unilateral and bilateral dynamic fixed state.

### Micro-computed tomography observation

The specimens were divided into two parts. One part was removed and thawed at room temperature. A rotary hard tissue slicing machine (Leica 1600) was used to cut off the heads of the screws as an ordinary saw may have affected the pedicle screws in the vertebral body. These were then prepared as bone specimens with pedicle screws.

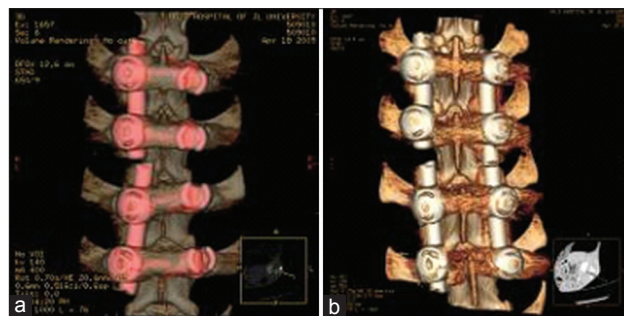
The bone specimens containing titanium pedicle screws were scanned by micro-CT (Locus SP microscopic CT, GE eXplore, USA), with the images then used in pathological studies. The scanned images were quantitatively and qualitatively analyzed using Micview V2.1.2 dimensional reconstruction software and ABA-specific bone analysis software. Measurement parameters were as follows: bone mineral content (BMC), bone mineral density (BMD), tissue mineralized content (TMC), tissue mineralized density (TMD), bone volume fraction (BVF), connectivity density (CD), and bone surface density (bone surface/bone volume [BS/BV]).

### Histomorphological observation

The bone specimens containing pedicle screws were embedded and sliced. After staining with ponceau trichrome and toluidine blue, the slices were observed under a microscope.

### Biomechanical observation

The other part of the vertebral body with pedicle screws was removed and thawed at room temperature. Soft tissue around the vertebral body was removed, keeping the spinous and transverse processes. Each vertebral body was placed into a special rectangle experiment slot, fixed by bone cement,



**Figure 2:** (a) The unilateral dynamic fixation group; (b) The static control group; (c) The bilateral dynamic fixation group.

and then placed in a universal material testing machine (AJ212 Shanghai), which could freely adjust the orientation of the sample. The pedicle screw pullout experiment was conducted at a speed of 5 mm/min after aligning the longitudinal axis and stress distribution of pedicle screws in the same direction. Test World V3.0 was used to process the mechanical data and mechanical curves.

### Statistical analysis

The SPSS 10.0 statistical software package (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. The BMC, BMD, TMC, TMD, BVF, CD, bone surface density, and pullout strength are presented as the mean  $\pm$  standard deviation (SD). Data from sample groups were compared using one-factor analysis of variance, and raw data of the sample groups were compared using the  $q$ -test. A two-sample  $t$ -test was used for comparison between any two groups. A  $P < 0.05$  was considered to be statistically significant.

## RESULTS

### Experimental animal imaging

There were no postoperative infections in any goat [Figure 3]. At 1 week postoperatively, CT reconstruction showed the position of pedicle screws in each goat's body was good, and most of the screws were in the pedicle and vertebral body [Figure 4]. There were three screws protruding through the medial pedicle bone cortex into the vertebral canal, but the affected goats did not show any movement disorders.

### Observation of the bone screw surface of the static control group using Ponceau trichrome staining

There was new bone formation in the cancellous bone around the pedicle screws in the static control group. The screw surface was rough, with mineral deposits on the surface. There was also new bone formation on the surface of screws [Figure 5].

### The morphological observation of pedicle screws of the unilateral dynamic fixation group

The pedicle screws were found to be loose after the fixed rods were removed in the unilateral dynamic fixation group. When fixing the slices, the screws inside the bone tissue fell out. Although, there was a large amount of connective tissue formation between and around the threads, there was no new bone formation on the surface of the screw.

### The morphological observation of pedicle screws of the bilateral dynamic fixation group

A large amount of connective tissue was found around the screw thread in the bilateral dynamic fixation group. However, there was no new bone formation. The fiber arrangement was well-organized, with many mineral deposits in the connective tissue [Figure 6].

### Micro-computed tomography observations

#### Micro-computed tomography qualitative observations of pedicle screws

The screw surface of the static control group was rough,



Figure 3: Postoperative breeding of experimental animals.

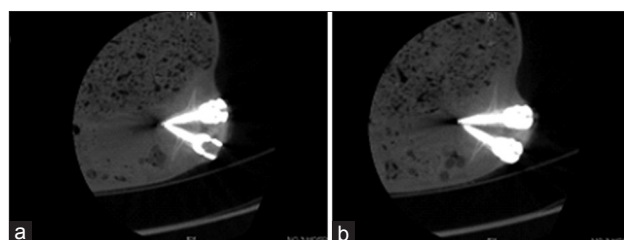


Figure 4: Axial observations of Cosmic pedicle screws in the goat lumbar spine.

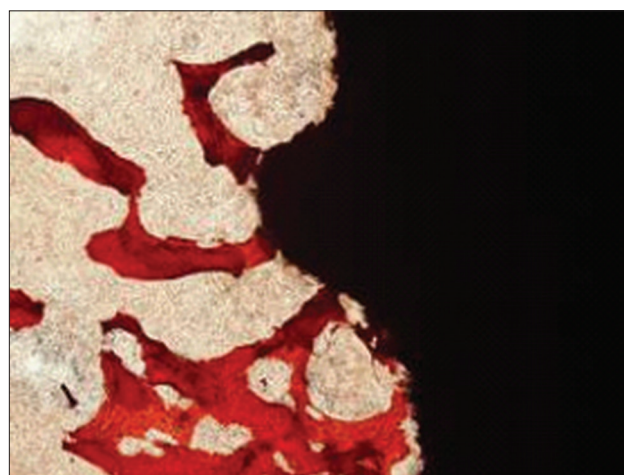


Figure 5: Ponceau trichrome staining of the static control group ( $\times 50$ ). There was new bone formation around the pedicle screw thread and on the screw surface.

indicating new bone formation on the screw surface and around bone tissue closely associated with the pedicle screw surface. Under unilateral and bilateral dynamic fixation states, the pedicle screw surface was smooth, indicating less bone combining with the surface [Figure 7].

#### Micro-computed tomography quantitative observations of pedicle screws

The BMD and morphological parameters of the region of interest (ROI) in the unilateral and bilateral dynamic

fixation groups were not significantly different from each other ( $P > 0.05$ ), but were significantly lower than the static control group ( $P < 0.05$ ). This indicates that the description bone of the ROI in the static control group was greater than in the unilateral and bilateral nonfusion fixation groups [Table 1].

### Biomechanical observation of the pedicle screws in each group

Under loading conditions, the maximum pull force of the pedicle screws in the bilateral ( $193.8 \pm 89.3$ ) and unilateral dynamic fixation groups ( $201.6 \pm 75.2$ ) was not significantly different ( $P > 0.05$ ). However, the maximum pull force of the fixation groups was significantly less than that of the static control group ( $633.3 \pm 143.4$ ) ( $P < 0.01$ ).

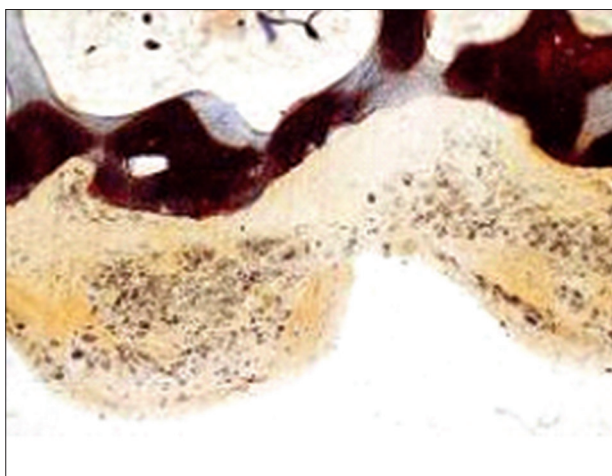
## DISCUSSION

Epidemiological studies show the percentage of people suffering from lower back pain and leg pain in some countries is 70%–85%.<sup>[13]</sup> When conservative treatment fails, spinal fusion, sometimes accompanied by neural decompression, is still considered the standard treatment for instability of lumbar vertebrae and lumbar disc herniation. However, spinal fusion by rigid instrumentation can have undesired side effects, such as accelerated degeneration of adjacent segments.<sup>[14,15]</sup> It is hypothesized that fusion of a motion segment leads to an overload and hypermobility of adjacent segments. Nonfusion devices, also known as

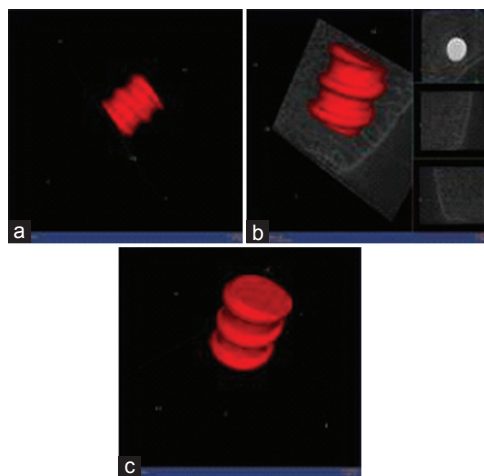
dynamic stabilization or motion preservation devices, aim to maintain or only moderately reduce the mobility of a motion segment and thereby decrease or eliminate adjacent level degeneration.

Many researchers have focused on the study of the biological mechanics of pedicle screw dynamic fixation systems. Research has indicated that the dynamic stability of the pedicle screw fixation system retains the activity of the fixed segment, reducing the stress concentration of the adjacent segments. From a biomechanical point of view, the pedicle screw dynamic fixation systems are applicable to spinal surgery.<sup>[2,7,16]</sup> However, there have yet been no reports about the bone-screw interface under dynamic fixation condition.

Screw loosening is a key issue in dynamic stabilization for lumbar degenerative disease. One research institution analyzed 658 screws used for lumbar dynamic stabilization in 126 patients with lumbar degenerative disease. In a mean follow-up period of 3 years, 31 screws (4.7%) in 25 patients (19.8%) became loose.<sup>[17]</sup> In rigid fixation constructs, the pedicle screws need to provide stabilizing strength only until bone fusion is achieved. However, a dynamic construct coupled with the bony interface requires more long-term durability as no bone graft incorporation ever occurs. Therefore, the longer the follow-up period, theoretically, the higher the rate of screw-loosening will be. Excess loading in a rigid fixation without bone fusion



**Figure 6:** Ponceau trichrome staining of the bilateral dynamic fixation group. Under the dynamic fixation state there was a large amount of connective tissue formed between pedicle screw threads, with no new bone formation. The fiber arrangement in the connective tissue was neat and contained many mineral deposits.



**Figure 7:** (a) The static control group; (b) The unilateral dynamic fixation group; (c) The bilateral dynamic fixation group. The pedicle screw surface of the static control group was relatively rough, whereas the unilateral and bilateral dynamic fixation pedicle screws had relatively smooth surfaces.

**Table 1: The Morphology and Bone Mineral Density Parameters of the Region of Interest in Each Group (mean  $\pm$  SD)**

	BMC (mg)	BMD (mg/ml)	TMC (mg)	TMD (mg/ml)	BVF (%)	CD	BS/BV (1/mm)
Bilateral dynamic fixation group	6.2 $\pm$ 1.3	121.7 $\pm$ 15.3	3.4 $\pm$ 1.3	503.9 $\pm$ 15.5	10.3 $\pm$ 5.3	4.1 $\pm$ 1.6	8.5 $\pm$ 0.4
Unilateral dynamic fixation group	5.3 $\pm$ 0.9	112.5 $\pm$ 8.8	3.1 $\pm$ 0.4	499.6 $\pm$ 6.6	9.4 $\pm$ 1.8	4.0 $\pm$ 1.9	9.1 $\pm$ 0.6
Static control group	15.3 $\pm$ 0.9	192.3 $\pm$ 18.9	8.9 $\pm$ 2.3	655.0 $\pm$ 15.3	18.2 $\pm$ 3.4	5.4 $\pm$ 1.4	10.5 $\pm$ 2.2

BMC: Bone mineral content; BMD: Bone mineral density; TMC: Tissue mineralized content; TMD: Tissue mineralized density; BVF: Bone volume fraction; CD: Connectivity density; BS: Bone surface; BV: Bone volume.

may cause implant breakage; however dynamic constructs are designed to shift rather than bear the entire loading of the lumbar spine. The cost of this flexibility is the need for more material strength and anchoring force at the interface.

In dynamic fixation surgery, a major problem in the initial stages of implanting the screw in the host bone is ensuring that there is good mechanical stability and a suitable physiological environment for new bone to form on the surface of the screw. When this environment is destroyed, fibrous tissue will form, and the osseointegration of the screw with surrounding bone tissue will possibly be lost. The force and fretting affect the process of the screw combining with the host bone tissue; the screw can only achieve maximum osseointegration with the surrounding bone tissue when in a stable environment.

In this study, fibrous connective tissue formation at the bone-screw interface was found under both unilateral and bilateral pedicle dynamic fixation; however, the screws did not achieve mechanical stability in the vertebrae.

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